UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,092	02/23/2004	Taru Blom	2630-126	3520

5514 7590 07/27/2006

FITZPATRICK CELLA HARPER & SCINTO
30 ROCKEFELLER PLAZA
NEW YORK, NY 10112

EXAMINER	
GEMBEH, SHIRLEY V	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 07/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/783,092	BLOM ET AL.	
	Examiner	Art Unit	
	Shirley V. Gembeh	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-11 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-11 is/are rejected.

7)☒ Claim(s) 3 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 5/20/04; 6/28/05.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement (IDS) submitted on May 20, 2004 and June 28, 2005 has been acknowledged and entered.

Status of Claims

Claims 1-11 are pending in this office action.

Claim Objections

Claim 3 is objected to under 37 CFR 1 .75 as being a substantial duplicate of claim 2. Because the compound of formula (1) in claim 2 is ospemifene, the scope of the claim is substantially same and both claims 1 and 2 are duplicates.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating osteoporosis, does not reasonably provide enablement for preventing osteoporosis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI

1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2nd 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a prima facie case are discussed below.

1) Nature of the invention.

The nature of the invention is directed to methods of treating/preventing in an individual suffering from increases bone turnover. As stated, however, claim 1 includes within its scope a wide variety of osteoporosis such as postmenopausal osteoporosis, senile osteoporosis (Primary), secondary osteoporosis, idiopathic juvenile osteoporosis (Primary), cancer related osteoporosis.

A. Prevention

There are several types of osteoporosis naming a few such as postmenopausal osteoporosis (primary), senile osteoporosis (Primary), secondary osteoporosis, idiopathic juvenile osteoporosis (Primary).

Up to date there is no one particular antibone loss agent that is effective to prevent the wide variety forms of bone disorder. (see

www.surgeongeneral.gov/library/bonehealth/chapter_9.html) page 2 key message. There is no one treatment, or combination of treatments which provides prevention (not occurring even the first time) of a bone disorder of anytime. The best prevention, however, is a life-long commitment to physical activity, good nutrition, and normal reproductive hormone status. (See www.endocrineweb.com/osteoporosis/treatment.htmlWeb), however, this is not prevention, all of which help reduce osteoporosis (for example one type of bone disease) but do not prevent.

As discussed below, (see http://www.endocrineweb.com/osteoporosis/treatment.html), teaches that researchers face the problem of sifting through potential conditional drugs for osteoporosis to find ones promising enough to make. Treatment of osteoporosis is classified in two groups and none of the drugs have proven themselves yet (see www.endocrineweb.com/osteoporosis/treatment.html). While the state of the art is relatively high with regard to the treatment of osteoporosis with specific agents, for a compound or genus to be effective against bone disease generally is contrary to medical science. Thus a considerable amount of invivo and invitro testing is required before the agent can be considered for a particular type of disease.

B. Chemotherapy

www.endocrineweb.com/osteoporosis/treatment.html teaches that There is no one treatment, or combination of treatments which provides prevention (not occurring even the first time) of fractures due to osteoporosis. At the present time, only anti-resorbers

are approved in the United States by the FDA for use in treating osteoporosis and none of the drugs in this group have demonstrated prevention.

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher,* 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statue. Further, their mode of action is often unknown or very unpredictable and administration of the drugs can be accompanied by undesirable side effects.

2) State of the prior art and the predictability or lack thereof in the art.

The state of the prior art is that it involves a myriad of diseases such as postmenopausal osteoporosis (primary), senile osteoporosis (Primary), secondary osteoporosis, idiopathic juvenile osteoporosis (Primary) thus preventing or treating will include screening *in vitro* and *in vivo* to determine the effect of the compound on the specific disease. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

3) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The quantity of experimentation needed is undue experimentation. One of ordinary skill in the art would first need to determine the type of conditions associated with bone

loss and then determine which of the thousands of compounds would be suitable for said treatment and/or prevention. Note that osteoporosis is only one such condition.

4) Level of predictability in the art.

The art pertaining to the treatment of all bone disease remain highly unpredictable. As disclosed above, there is no absolute predictability even in view of the seemingly high level of skill in the art. Firstly, for a compound or genus to be effective against oesteoporosis for example or a bone disease generally is contrary to medical science. Conditions associated with bone disease is a process that can take place in virtually any part of the body. There is a vast range of forms that it can take, causes for the problem, and biochemical pathways that mediate the conditions associated with bone loss reaction. Accordingly, treatments for conditions associated with bone loss/bone mass density are normally tailored to the particular type of of mediator present.

5) Breadth of claims.

Claim 1 is extremely broad due to the vast number of possible diseases encompassed by the instant invention.

6) Level of ordinary skill in the art.

Due to the unpredictability in the pharmaceutical art (see reference www.endocrineweb.com/osteoporosis/treatment.htmlWeb), it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by *in vitro* and *in vivo* screening to determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

Hence, the specification fails to provide sufficient support of the broad use of the compounds of the claims for the treatment of any disease. As a result necessitating

one of ordinary skill in the art to perform an exhaustive search to determine which diseases can be treated by what compounds of the instant claims in order to practice the claimed invention.

II. Claims 1, 4-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

A lack of adequate written description issue arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process. See, e.g., Fujikawa v. Wattanasin, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) (a "laundry list" disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not "reasonably lead" those skilled in the art to any particular species); In re Ruschig, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967).

Applicant has not provided a description of the structure of a representative number of compounds nor a description of the chemical and/or physical characteristics of a representative number of compounds nor a description of how to obtain a representative number of specific compounds.

In other words, the Applicant has not described with sufficient clarity a therapeutic active compound, which is a selective estrogen receptor modulator of triphenylalkene or

triphenylalkane structure. To overcome this rejection Examiner suggest the inclusion of the limitation of claim 2 into claim 1.

The following is a quotation of the second paragraph of 35 U.S.C. 112:second

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

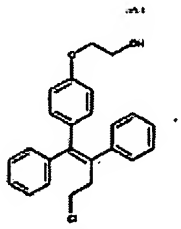
Claims 1 and 5-6 are rejected under 35 U.S.C. 1 12, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites the limitation values for these markers " in claim 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-2 and 4 are rejected under 35 U.S.C. 102(a) as being anticipated by Jordan, J. Medicinal Chem.



(30)

Jordan teaches the same structurally identical compound in the instant claim 2, that demonstrates selective estrogen receptor modulator (SERM) activity in bone administering an effective amount (see page 1088, right col. item (f) in post menopausal women as in claim 4.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Halonen et al. US 6,245,819 ('819).

Halonen et al. (US'819 hereafter) teaches FC1271(=deaminohydroxytoremifene) as well as active metabolites, geometric isomers or stereoisomers thereof, (see column 2, lines 35-39) as in claims 1-3. The reference also teaches use in treatment of osteoporosis in menopausal women (see col. 5 lines 28-35) as in claims 1 and 4.
(It is noted that ospemifene is FC1271(=deaminohydroxytoremifene) that has the chemical structure recited in instant claim 2.
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SVG
7/17/06

Ardin H. Marschel 7/24/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER